

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Amendments to the Specification

The specification is amended to add trademark symbols, as requested in the Office Action.

Claim Amendments

Claims 1-63 stand canceled without prejudice or disclaimer.

Claims 64, 77 and 78 are amended. No new matter is added by the amendments. Support for the amendments can be found throughout the application as filed, as follows.

Consistent with the suggestion by the Office, claim 64 is amended to make clerical changes to the preamble. The phrase “substantially insoluble in and impermeable to fluids during the indented release period” is replaced with “insoluble in and impermeable to aqueous media,” as taught, for example, at page 7, line 5. Claim 64 is further amended recite that “the matrix composition does not comprise a surface active agent.” Support for this aspect of the claimed invention can be found, for example, at page 9, lines 1-23, of the application as filed.

Claim 77 is amended to correct a minor typographical error.

Claim 78 is amended to delete the phrase “an equivalently effective opioid.”

These amendments are made without prejudice or disclaimer. Applicants reserve the right to pursue any canceled subject matter in one or more continuing application(s) with the same rights of priority as the instant application.

Upon entry of the amendments, claims 64-81 will remain pending. These claims are presented for reconsideration.

Priority

Applicants thank the Office for acknowledging the foreign priority claim based on the application filed in Denmark on March 26, 2003.

Information Disclosure Statement

Applicants thank the Office for acknowledging the Information Disclosure Statements (IDSs) submitted on September 26, 2005 and July 16, 2009. Regarding the Office's objection to the citations of German documents A34 (DE 2332484) and A35 (DE 2415490), Applicants provide English language equivalents GB 1430684A and US 3,957,523, respectively, in an IDS submitted herewith. Consideration of these references is respectfully requested.

Objection to the Specification

Consistent with the suggestion by the Office, Applicants have amended the specification to capitalize the trademarks. However, Applicants believe that accompaniment of the trademark by the generic terminology, as requested by the Office, is not necessary here since the trademarks used in the specification have a fixed and definite meaning. As set forth in MPEP § 608.01(v), if the trademark has a fixed and definite meaning, it constitutes sufficient identification unless some physical or chemical characteristic of the article or material is involved in the invention. It is only in that event, or in those cases where the trademark has no fixed and definite meaning, identification by scientific or other explanatory language is necessary. *In re Gebauer-Fuelnegg*, 121 F.2d 505, 50 USPQ 125 (CCPA 1941). In the present case, the trademarks identify commercial drug products that are cited in comparison to the described invention. The trademarks have a fixed and definite meaning and are not involved in the invention. Moreover, the meaning is evident from the context of their use in the specification.

Applicants believe that in light of the amendments, this objection has been obviated.

Claim Objections

Claim 77 was objected to because the claim was missing a period at the end of the sentence. Applicants thank the Office for pointing out the minor typographical error. An appropriate correction has been made.

Enablement Rejections

Claims 64-77 and 79-81 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Office alleges that the recitation of “an opioid” in the claim makes it a “reach through” claim. In particular, the Office alleges that the claims read on “opioids yet to be invented.” Applicants traverse this rejection.

The term “opioid” refers to a known class of chemical compounds that bind to opioid receptors. See, e.g., Specification, page 21, line 10. The application as filed includes a substantial list of exemplary opioids at pages 5-6. The Office Action has not established why the skilled artisan would not be able to practice the claimed invention with regard to the selection of a suitable opioid without an undue amount of experimentation.

MPEP § 2164.05(a) makes clear that enablement is assessed as of the filing date. Thus, whether or not the specification enables the use of “opioids yet to be invented” is irrelevant to the enablement inquiry. Moreover, the Office Action makes no showing as to why it would require undue experimentation to formulate any opioid, known or as yet to be invented, in a composition as recited in the claims.

MPEP § 2164 explains that the enablement requirement holds that the specification must describe how to make and use the claimed invention. Detailed procedures need not be set forth as long as the description is sufficient to permit those skilled in the art to practice the invention without an undue amount of experimentation. Thus, a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Here, the specification clearly describes how to make and use the invention with regard to the selection of an opioid, providing numerous examples of suitable opioids, and working examples using morphine as an exemplary opioid. Indeed, the Office Action raises no rejection with regard to enablement of currently known opioids. Therefore, the specification satisfies the enablement requirement, and this rejection should be withdrawn.

Indefiniteness Rejections

Claims 64, 67, and 78 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants address the issues in turn below.

A. The Office recommends adding the term “and” or “that is” between the terms “pain” and “sensitive” and adding a comma before the term ‘comprising.’ in claim 64. Without acquiescing to the propriety of the rejection and solely to expedite prosecution, Applicants have made the suggested amendments to claim 64. Withdrawal of this rejection is respectfully requested.

B. The Office alleges that the term “substantially insoluble” is unclear in claim 64. Without acquiescing to the propriety of the rejection and solely to expedite prosecution, Applicants have amended claim 64 to remove the term “substantially.” Withdrawal of this rejection is respectfully requested.

C. The Office further alleges that it is unclear what period of time is encompassed by “intended release period” in claim 64. Without acquiescing to the propriety of the rejection and solely to expedite prosecution, Applicants have amended claim 64 to delete this phrase. Withdrawal of this rejection is respectfully requested.

D. The Office alleges that it is unclear what is a minimum requirement or a measurable or a quantifiable scale for “less side effects” in claim 67. Applicants traverse this rejection. This aspect of the invention is discussed, for example, at page 3, lines 26-37. As set forth there, advantageous properties achieved by the present invention (such as the ability to achieve effective pain relief with a low serum opioid concentration) may be associated with fewer side effects, such as sedation, nausea, dizziness, and others listed at page 3 and in claim 68. Such side effects are routinely assessed and reported in clinical trials, and those skilled in the art will not find the recitation of “less side effects” to be indefinite. Thus, withdrawal of this rejection is respectfully requested.

E. The Office alleges that it is unclear which opioids are included or excluded from being “equally effective opioid” in claim 78. Without acquiescing to the propriety of

the rejection and solely to expedite prosecution, Applicants have amended claim 78 to cancel the objected phrase. Withdrawal of this rejection is respectfully requested.

Claim Rejections Under 35 U.S.C. § 102

1. Claims 64-65 and 79-81 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Bar-Shalom et al. (US 5,213,808). Applicants traverse the rejection in as much as it may be applied to the pending claims.

As reflected in independent claim 64, the instant claims are directed to methods for treating a patient suffering from pain that is sensitive to an opioid comprising orally an opioid in a controlled release pharmaceutical composition comprising a matrix composition comprising (a) a polymer or a mixture of polymers, (b) an opioid, and optionally, (c) one or more pharmaceutically acceptable excipients, wherein the matrix composition does not comprise a surface active agent. The matrix is provided with a coating that is insoluble in and impermeable to aqueous media and that comprises a polymer from a recited list. The coating has at least one opening exposing at least one surface of the matrix, thereby allowing controlled release of said opioid by erosion of said matrix surface. Bar-Shalom does not teach such compositions or methods using them

For example, Bar-Shalom does not teach a composition that does not include a surface active agent (or mixture of surface active agents) in the matrix. To the contrary, Bar-Shalom teaches compositions comprising surface active agents in order to limit diffusion of water into the composition so that erosion is predominantly effected by the dissolving action of the aqueous phase on the exposed surface, in order to provide constant and controlled release. *See* Bar-Shalom, col. 11-14, and col 11, line 69 – col. 12, line 19, in particular. Indeed, all of the examples of Bar-Shalom illustrate compositions that contain a surface active agent (PEG 400 monostearate) in the matrix. Such compositions are excluded from the instant claims.

Because Bar-Shalom does not teach compositions within the scope of the instant claims, this rejection should be withdrawn.

2. Claims 64-68 and 76-81 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Fischer et al. (US 2004/0253310). Applicants traverse the rejection in as much as it may be applied to the pending claims.

Fischer does not qualify as a prior art reference under 35 U.S.C. § 102(e) because it is not an application filed by “another.” Fischer names the same inventors as the instant application: Gina Fisher, Daniel Bar-Shalom, Lillian Slot and Christine Jensen. Withdrawal of this rejection therefore is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

1. Claims 69-75 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fischer et al. (US 2004/0253310).

As set forth above, Fisher does not qualify as prior art against the instant application, because it is not an application by “another.” Thus, Fisher cannot be applied against the pending claims in a §103 rejection. Withdrawal of this rejection therefore is respectfully requested.

2. Claims 66-78 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bar-Shalom et al. (US 5,213,808) in view of Fischer et al. (US 2004/0253310).

As set forth above, Fisher does not qualify as prior art against the instant application, because it is not an application by “another.” Thus, Fisher cannot be applied against the pending claims in a §103 rejection. Withdrawal of this rejection therefore is respectfully requested.

Obviousness-Type Double Patenting Rejections

1. Claims 64-81 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 3-47, and 49-71 of co-pending Application No. 10/550,685 (the '685 Application).

2. Claims 64-81 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 60-100 of co-pending Application No. 12/078,312 (the '312 Application).

Applicants note that these are provisional rejections, and therefore defer these issues until the application is otherwise in condition for allowance. Since any claim amendments made in any of these applications may impact the obviousness-type double patent inquiry, addressing the rejections on the merits now would be premature.

CONCLUSION

Applicants believe that the application is in condition for allowance, and favorable reconsideration is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance prosecution.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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